K123769

MAY 10 2013

SPINERGY

*Faster by Design!*

**"510(K) SUMMARY"**
**AS REQUIRED BY SECTION 807.92(c)**
Modified May 1, 2013

**510(k) Owner's Name, Address, Telephone Number, Fax Number, Contact Person and Date Prepared.**

SM Power, LLC, an affiliate of
Spinergy, Inc.
1914 Palomar Oak Way
Carlsbad, CA. 92008
Phone: (760) 496-2121
Fax: (760) 496-2153

Contact Person:

Edward A. Kroll
President, Spectre Solutions, Inc. and
Representative Consultant for
Spinergy, Inc.
5905 Fawn Lane
Cleveland, Ohio 44141
Phone: (440) 546-9801
Fax: (440) 546-9124

Date Prepared: February 10, 2013

**Name of Device**

- Trade Name: ZX-1 Power Add On
- Common Name: Manual Wheelchair Power Add On
- Classification Name: Wheelchair, Powered (21 CFR 890.3860) Product Code: ITI

**Predicate Device**

Albers E-Fix Conversion Kit (K943789)

**Device Description:**

The ZX-1 Power Add On is a light duty, power add-on device with the purpose of delivering powered mobility to a manual wheelchair. The device easily attaches/detaches to the frame of a manual wheelchair.

The engagement between the ZX-1 and the manual wheelchair is accomplished without the need for hardware or other fixed attachment devices.

The user remains seated in their manual wheelchair and performs a simple maneuver to attach the ZX-1 to their manual wheelchair. Once securely attached to the ZX-1, the user negotiates the speed and direction of their wheelchair by using a VR2 joystick controller attached to the arm rest of the ZX-1.

**Device Function**

The device consists primarily of a stainless steel base with drive wheels, a power module with joystick, two drive motors, a connector mechanism, two armrests and an anti-tilt assembly. It functions by connecting to the host manual wheelchair rear camber tube. Once the connection is made, the linear actuator lifts the manual wheelchair rear wheels slightly off the ground and onto the stainless steel base with drive wheels.

Power to the drive motors is supplied by use of the joystick which is used to engage wheelchair motion and steer the chair. During use, the ZX-1 offers forward, reverse and 360 degree turning maneuverability. The user is able to adjust the speed setting to meet their needs and level of comfort.

**Scientific Concepts**

The ZX-1 incorporates basic electro-mechanical drive technology. It is powered by two 12VDC, permanent magnet motor/gearboxes with brakes. The motors are controlled using a joystick/controller combination that is specifically designed for use with powered wheelchairs and scooters.

**Significant Physical and Performance Characteristics**

Design:

- Maximum speed 3.2mph.
- May be used both indoors and outdoors
- Maximum operation incline 6 degrees
- Highest curb clearance 2 inches (50mm).
- Maximum patient weight capacity is 250 lbs.

Materials:

- Stainless Steel Base
- Rubber Drive Wheels
- Carbon Fiber Plastic Cover

- Physical Properties:

  The ZX-1 can be used with any manual wheelchair with the following characteristics.

  - Rigid frame with a horizontal, round camber tube
  - Camber tube must be mounted level with wheelchair rear wheel axles
  - No obstructions under camber tube
  - 24", 25" or 26" wheelchair rear wheels
  - 15"-20" rear seat width (14" can be used with some configurations)
  - Minimum of 6" between camber tube and front caster wheels or footplate

**Intended Use/Indications for Use**

The ZX-1 is intended to provide enhanced mobility to disabled persons who are capable of operating a powered and manual wheelchair, by providing powered mobility to manual wheelchairs.

**Predicate Device Comparison**

The ZX-1 Power Add On is substantially equivalent to the Albers Technologies, Inc. "E-Fix", Power Wheelchair Conversion Kit (E-Fix). This device was granted marketing clearance by FDA on November 8, 1994, under 510(k) Accession Number K943789.

Both of these products are electrically powered, motor driven devices with the intended function and use of providing powered mobility to manual wheelchairs. They are constructed from the same basic materials, incorporate the same operational principles and both use two, 12 VDC batteries as their power source. Additionally, both devices include a joystick operated motor controller to engage system motion and steer the wheelchair. See Tables 1 and 2 below for similarities and differences.

**Performance Data: (Non-clinical Testing)**

The ZX-1 Power Add On has been tested to and meets the requirements specified in the Rehabilitation Engineering Society of North America (RESNA) Standard ANSI/RESNA WC/14 (1991) and ISO Standard ISO 7176: 1993(E), "ISO Standard, Wheelchairs - Requirements and Test Methods for the Power and Control Systems of Electric Wheelchairs."

Additionally, Spinergy has conducted Leakage Current Testing in accordance with the IEC 60601-1 Standard for Medical Equipment. Results confirm that leakage current is less than the 100 Amp maximum value specified in the Powered Wheelchair and Scooter 510(k) Guidance Document.

Finally, Spinergy has conducted EMC Testing in accordance with EN55011/A2:2007, IEC 60601-1-2:2007 (Modified) and American National Standard: Requirements and

Test Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Motorized Scooters RESNA WC-2:2009 Standard Section 21:

**Conclusion:**

The Spinergy ZX-1 Power Add On is substantially equivalent to and is as safe and effective as its predicate device. They have the same indications for use, are constructed from the same basic materials and both incorporate the same operational principles.

Results of performance tests conducted on the ZX-1 clearly demonstrate that the device is safe and effective for its intended use.

# TABLE 1

| SIMILARITIES | |
|---|---|
| *Indications for Use* | |
| **Spinergy ZX-1 Power Add On** | **Alber Technologies E-Fix (K943789)** |
| The Zx-1 is intended to provide enhanced mobility to disabled persons who are capable of operating a powered and manual wheelchair, by providing powered mobility to manual wheelchairs | The E-Fix is intended to aid disabled individuals by increasing their mobility |
| *General Similarities:* | |
| **Spinergy ZX-1 Power Add On** | **Alber Technologies E-Fix (K943789)** |
| The ZX-1 is basically a kit intended to be attached to an existing manual wheelchair | Same |
| Major components of the ZX-1 are wheels, frame, motors, motor controller, joystick, rechargeable batteries | Same |
| Free Wheel Mode which disables the drive motors and allows the device to be attendant propelled when the power-conversion device is attached | Same |
| The ZX-1 kit may be removed altogether and the host wheelchair restored to its status as a manual wheelchair | Same |
| The ZX-1 may be used both indoors and outdoors | Same |
| Power wheelchair operation is carried out by the user and not by an attendant. | Same |
| *Technology:* | |
| **Spinergy ZX-1 Power Add On** | **Alber Technologies E-Fix (K943789)** |
| Basic electro-mechanical drive technology consisting of two drive motors and basic gear reduction | Same |
| Motors are controlled using a microprocessor based motor controller | Same |
| The microprocessor automatically controls the speed of acceleration and deceleration | Same |
| Power source is two 12 VDC batteries | Same |
| Joystick control to engage motion and steer the chair | Same |
| *Features/Specifications:* | |
| **Spinergy ZX-1 Power Add On** | **Alber Technologies E-Fix (K943789)** |
| Weight limitation of 250 pounds | Same |
| Maximum speed of 3.2 mph | Maximum speed of 3.7 mph (Minor difference of .5mph is negligible) |
| Operating voltage is 24 VDC | Same |
| Hand-operated horn | Same |
| Battery level indicator | Same |
| On/Off switch | Same |

## TABLE 2

| DIFFERENCES | | | |
|---|---|---|---|
| **Description:** | **Spinergy ZX-1 Power Add On** | **Alber Technologies E-Fix (K943789)** | **Discussion** |
| Wheel configuration | 4 wheels: 1 rear anti-tip, 1 front lift wheel. 2 (10") central drive wheels | 2 main drive wheels | Both devices utilize centrally located drive wheels and maintain usage of the host wheelchair's front casters. Therefore, they are substantially equivalent in this respect. |
| Mechanism to attach/detach to wheelchair | Mechanized clamp attaches/detaches to manual wheelchair frame | Manually attached/detach E-Fix wheels and standard rear wheels. | The ZX-1 attach/detach process is motorized while the E-Fix wheels are attached/detached manually. This does not affect safety as the ZX-1does not operate unless the connection has been made and confirmed via the device software. |
| Brake mechanism | Electromagnetic braking system and disk park brake. | Electronic engine breaking system, spring loaded drum brakes and the original wheelchair brake. | While the E-Fix claims to have 3 braking systems it is relying on the host wheelchair hand brake as one of them. Therefore, there are only two brakes in the device itself and they are similar to the ZX-1. The engine brake functions in the same manner as the ZX-1 electromagnetic brake in that both go into effect whenever the joystick control is returned to its neutral, central position. The E-fix drum brake functions in the same manner as the ZX-1 disk park brake in that both brakes become engaged once the wheelchair comes to a stop. |
| Theoretical driving range | 5.0 mi. | Up to 12 miles depending on the weight of the person. Typical range is 15.5 miles. | The E-Fix will travel further between charges. This has no effect on safety or effectiveness as battery depletion is still possible for both devices. The ZX-1 battery indicator flashes red when the batteries are near depletion. If the batteries fail, the ZX-1 may be placed in free wheel mode and can be moved. If the E-Fix batteries fail it can be reset to manual mode and can be moved. Therefore, they are equivalent in this respect. |
| Battery Mount | Self-contained battery | Docking battery pack | ZX-1 battery is permanently mounted to the ZX-1 frame. E-Fix is contained in a battery pack which mounts to the rear of the host wheelchair. This does not deleteriously affect safety. With the E-Fix the user is more likely to be exposed to the battery than with the ZX-1. |
| Host Wheelchair Requirements | Used only with a rigid frame manual wheelchair. Cannot be used with a folding frame manual wheelchair | Adapts to both a rigid frame and folding frame manual wheelchair | This has no effect on safety or effectiveness. It only limits the type of wheelchair with which the ZX-1 can be used. The ZX-1 labeling clearly states that it cannot be used with a folding frame manual wheelchair. |
| Free Wheel Operation | Attendant propelled, only | Can be both user propelled and attendant propelled. | This has no effect on safety or effectiveness. Free wheel mode is intended to permit the device to be moved manually, if needed. Should the user for some reason be unable to operate the chair in power mode, it is likely he/she would not be able to self-propel the wheelchair and would require attendant assistance. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 10, 2013

Spinergy, Inc.
C/O Spectre Solutions, Inc.
ATTN: Edward A. Kroll
5905 Fawn Lane
Cleveland, Ohio 44141

Re: K123769
Trade/Device Name: ZX-1 Power Add On
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: March 19, 2013
Received: March 22, 2013

Dear Mr. Kroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to: http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**Indications for** Use

510(k) Number (if known): K123769

Device Name: ZX-1 Power Add On

Indications for Use:

The ZX-1 is intended to provide enhanced mobility to disabled persons who are capable of operating a powered and manual wheelchair, by providing powered mobility to manual wheelchairs.

| Prescription Use X (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use (21 CFR 801 Subpart C) |
|---|---|---|

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)
510(k) Number K123769